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UNCLAS SECTION 01 OF 02 MANILA 005447

SIPDIS

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STATE FOR EAP/MTS
STATE PASS TO USTR FOR BWEISEL AND DKATZ
STATE PASS TO USAID FOR CDOWNEY
USDOC FOR 4430/ITA/MAC/DBISBEE
USDOC PASS TO USPTO FOR PFOWLER, KHAUDA

E.O. 12958: N/A
TAGS: ECON ETRD KIPR BEXP RP
SUBJECT: PHARMACEUTICAL PATENT PROTECTION ON THE CHOPPING BLOCK

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SUMMARY

¶1. (SBU) Senator Manuel Roxas, Chairman of the Senate Committee on Economic Affairs and the Committee on Trade and Commerce, introduced a bill last month proposing amendments to the RP's Intellectual Property Code (IP) that could significantly weaken intellectual property rights protection for pharmaceutical products. The bill would further liberalize the compulsory licensing provision, allow the "early use" of patented drugs by potential generic manufacturers, and expand parallel importation. Committee hearings on SB2139 are scheduled to start this week. Embassy has written to Roxas expressing our concern and are trying to meet with him at the earliest opportunity. End Summary.

SENATE BILL WEAKENS DRUG PATENT PROTECTIONS

¶2. (U) Senator Manuel ("Mar") Roxas, Chairman of the Senate Committee on Economic Affairs and the Committee on Trade and Commerce, introduced a bill last month (SB2139) to amend the Intellectual Property Code (IP) of the Philippines. Based on conversations with GRP officials and industry representatives, Embassy understands that the bill proposes three major changes that could significantly weaken intellectual property rights protection for pharmaceutical products. First, it would liberalize compulsory licensing by immediately allowing exceptions when drugs or medicines are to "protect public health." Current compulsory licensing provisions involve a lengthy bureaucratic process. Since the law's inception in 1998, only four cases have been filed.

¶3. (U) Second, the bill includes an "early use" provision that would allow the experimentation, production and registration of a patented drug and its data before the expiration of the patent. This would permit manufacturers to make and sell the drug as a generic immediately after patent expiration. Current law provides patent protection for a product from the date of patent approval in the Philippines, provided that the patent application is filed within one year of the product's introduction to the world market. The Roxas proposal would nullify any advantage to filing a local patent in the Philippines and reduce the overall period of patent protection.

¶4. (U) Third, the Roxas bill would allow parallel importation of drugs and medicine by the government, again under the umbrella of "public health," upon application to the Intellectual Property Office (IPO), regardless of whether the imported product is protected by a local patent. Currently, parallel imports are not allowed for products under patent protection in the Philippines. The Roxas proposal, therefore, expands parallel imports by eliminating local patent protection on imported medicines. In addition, the bill prohibits the ability of a rights holder to apply for an additional patent for a "new use" discovered for a drug with an existing patent.

DIVERGENT VIEWS ON PATENT PROTECTION NEEDS

¶5. (SBU) In mid-October, the GRP co-sponsored a forum on public health with the Philippine Chamber of the Pharmaceutical Industry (PCPI), a local industry advocacy group composed of Philippine generic manufacturers, to "examine flexibilities" in the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) with respect to patents, including compulsory licensing, early use

provisions, and allowances for parallel importation. Although Embassy was not invited to the event, the Pharmaceutical and Healthcare Association of the Philippines (PHAP), an industry association with members holding U.S. patent rights, said the forum was attended by pharmaceutical industry representatives, officials from the Department of Trade and Industry, Department of Health and the Bureau of Food and Drugs, the Chair of the House Committee on Trade and Industry, and the Vice-Chair of the House Committee on Health.

¶6. (SBU) Ireneo Galicia, Deputy Director General at the Intellectual Property Office, told Econoff that the Roxas bill was "mentioned" at the forum and a "brief description of the salient points of the bill" was provided. According to Galicia, Senator Roxas sees patents as the main cause behind high medicine costs. However, one of the forum briefing papers, submitted by IPO itself, expressed "a growing concern that the TRIPS standards for intellectual property rights may have negative implications with regard to affordability and access to medicines, especially in the Philippines." Galicia commented that Roxas does not necessarily take into account other factors such as production prices. Galicia noted that the IPO tried to "disabuse" attendees of the notion that patents are the only problem. He said the forum helped Roxas understand there are other ways to reduce medicine prices. Galicia still expects committee hearings to move forward on the Roxas bill, however.

¶7. (SBU) Representatives from Pfizer and from PHAP had a completely different assessment of the forum, expressing dissatisfaction with the way it was organized and a general feeling that the cards were stacked against patent holding pharmaceutical companies. PHAP indicated that industry representatives, aside from those of the local PCPI, were given very little time to speak and felt that their views were not heard. Pfizer expressed similar concerns, noting that it seemed like the forum was organized so as to garner support for the Roxas bill rather than to provide a balanced discussion of alternative ways to reduce medicine costs.

¶8. (SBU) Overall, Galicia said the forum highlighted the need for the IPO to revisit pertinent rules and regulations, as well as business processes, in order to improve overall efficiency and effectiveness. Specifically, IPO needs to reexamine whether "issued patents are of good quality" (meaning that IPO is issuing patents appropriately) and whether rules are being applied uniformly. In the meanwhile, SB2139 will move forward to committee hearings this week. Rumor has it that Representative Ferjenel Biron, Vice-Chair of the House Committee on Health, intends to file a counter-bill in the House that closely models the Senate version.

¶9. (U) Embassy has written to Senator Roxas expressing USG concern with the legislation and Econ Counselor has requested a meeting with him to underscore these concerns.

COMMENT

¶10. (SBU) The Roxas bill is especially troubling to U.S. pharmaceutical rights holders who are trying to retain their market share and profitability in the Philippines. While the bill taps into more flexible provisions in TRIPS, it may not offer enough protection for drug makers. Passage of the bill would not reflect well on the Philippines' efforts to improve IPR and be removed from USTR's Special 301 Priority Watch List, following its out-of-cycle review this January. U.S. pharmaceutical patent holders, represented by PHAP, may defuse concerns about the high drug costs and the potential for an avian flu pandemic by focusing on alternate ways to reduce the cost of medicine, and support information exchange and planning to address any potential pandemic.

JONES